TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
INTERNATIONAL PAPER)

Pages: 1 through 29

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UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
INTERNATIONAL PAPER)

Training Room 1
4700 River Road
Riverdale, Maryland

Thursday,
March 11, 2004

The parties met, pursuant to the notice, at 10:39 a.m.

ATTENDEES:

For the USDA, Animal & Plant Health Inspection Service (APHIS) and Biotechnology Regulatory Services (BRS)

REBECCA BECH, Associate Deputy Administrator
JOHN TURNER, Director of Policy Coordination
LAURA BARTLEY
DAVID BENNETT
TERRI DUNAHAY
JUDY GARRISON
SUBHASH GUPTA
LEE HANDLEY
NEIL HOFFMAN
SUSAN KOEHLER
SALLY MCCAMMON
VIRGIL MEIER
HALLIE PICKHARDT
BOB ROSE
ROBIN ROSE
CRAIG ROSELAND
MICHAEL WACH
MICHAEL WATSON
CHRIS ZAKARKA

ATTENDEES (Cont'd.)

For International Paper:

MARY M. MANN, Washington Representative, Public Affairs

JAMES L. RAKESTRAW, Ph.D., Manager, Forest Research

P R O C E E D I N G S

(10:39 a.m.)

MR. TURNER: Okay. I'm going to open things up, then I'll turn it over to you guys, and we can let this go wherever you want, whatever is helpful. First off, welcome to our stakeholder discussion series on our upcoming EIS and revised plant biotech rule. We certainly want to thank you for taking times from your busy schedules to meet with us.

The purpose of these briefings is to share information regarding our plants, to develop an environmental impact statement and amend our plant biotechnology regulations and to gather information and informative input which will support thoughtful and effective decision making on our part in the development of our new regulations.

We have here members of the BRS management team, as well as members of our staff, and when available, other key agency personnel involved in supporting BRS in this effort. In terms of key individuals who will be working on the EIS, I'm one. I've been around here awhile in a number of positions for five years. I'm John Turner. My normal position is director of the policy coordination unit, but I'm going to be working full time on the environmental

impact statement and then the regulations for the near future, or maybe the long-term future.

Also, a new hire, another key individual who is going to be full time is Michael Wach, here to my left. Michael is an environmental protection specialist within the environmental and ecological analysis unit here. In addition to possessing a Ph.D. and an environmental law J.D., Mike brings experience in plant pathology and weed science, as well as legal experience, working on cases involving NEPA, the Clean Water Act, the Clean Air Act, and other environmental laws.

As you may know, we participated in interagency discussions with FDA, EPA and the White House, which, while concluding that the coordinated framework has done an outstanding job to date in guiding the regulation of biotechnology, recognizing the Plant Protection Act of 2000 provides a unique opportunity for APHIS to revise its regulation and potentially expand our authority, while leveraging the experience that we've gained through our years in regulating biotechnology.

There was discussions on some general agreement on how the biotech regulatory approach would evolve, but still there is much opportunity for public

and stakeholder input as we move forward and develop the specifics.

Given this, what we would like to do at these meetings is to have an opportunity to hear your thoughts, as well as an informal give and take of ideas. It's a unique opportunity to do this at this time because it's still early in the process, and we've not yet engaged in the formal rule making phase, so we're free to speak openly and exchange ideas with stakeholders and the public.

Our discussion is being transcribed for two reasons. First is so that we'll have an accurate record of our discussions to refer to. Secondly, in the interest of transparency and fairness to all stakeholders, we'll be making available as part of the record and possibly on our website all of this documentation. Everyone can benefit from the discussions that we have with each of the stakeholders.

I also want to emphasize that while we're happy to share with you our current thinking on the process, it's an evolving process, and it's likely to change over time. So in addition to input from stakeholders and the public, we'll be getting input from our administrator, the undersecretary, our office

of general counsel, and of course, the secretary of agriculture. These will provide insightful direction to us as well.

So while we value the input, it's important to recognize that we may have an enthusiastic discussion today over some aspect of the regulations, but it's an evolving process, immediately changing. What we do know, we can talk about some BRS priority areas that are going to guide us in their vision of our regulations. One is rigorous regulation, which thoroughly and appropriately evaluates and ensures safety and is supported by strong compliance and enforcement.

The second is transparency of the regulatory process and decision making to stakeholders and the public. This is critical for public confidence. Thirdly, we must have a scientific-based system, ensuring that the best science is used to support regulatory decision making to assure safety. Fourth, communication, coordination and collaboration with the full range of stakeholders. Last I would mention international leadership. We have to ensure that international biotech standards are science-based, as are ours.

We need to support international regulatory

capacity building, and we have to consider international implications of policy and regulatory decisions that we make here at home.

As we prepare to begin our discussions, I would let everyone know that for effective transcription, the first time you speak if you could just state your name. Then after that, it's not necessary. With that, I would like to open up the floor to hear your comments and discussion.

MR. RAKESTRAW: Thank you. I am Jim Rakestraw, manager of forest research and technology for International Paper. I'm located in Savannah, Georgia. To my right is Mary Mann from our Washington office. Mary, would you?

MS. MANN: Good morning.

MR. RAKESTRAW: Well, thank you for the opportunity to appear before you this morning. International Paper supports APHIS' intent of its regulatory framework pertaining to importation, transportation and environmental release of products developed through biotechnology. International Paper, IP, is the world's largest paper and forest products company headquartered in the United States. We have operations in over 40 countries and sell our products in more than 120 nations.

In the U.S., IP owns or controls approximately 9,000,000 acres of forest land, with the majority of those lands located in the southeast. International Paper forester is an ecologist manager for us with great care in compliance with the rigorous standards of the sustainable forestry initiative, which ensures the perpetual planting, growing and harvesting of trees while protecting wildlife by diversity: plants, soils, water and air quality.

All of International Paper's U.S. forest lands are SFI certified by an independent third party. Given our company's significant presence throughout the United States, our reliance on science based sustainable environmental practices and our financial responsibilities to local communities and shareholders, we respectfully submit our perspectives on potential regulatory changes affecting biotechnology.

International Paper believes that APHIS' current system for assessing the potential environmental risks of products developed through biotechnology has been highly effective. The success of this approach is demonstrated by thousands of biotech field trials that have been conducted and dozens of biotech products that have been

commercialized without any adverse effect on human health or the environment.

The fact that products derived through biotechnology have been exported from the United States without any adverse effects demonstrates that APHIS has been successful in safeguarding human health and the environment, not only in the United States but worldwide. Under APHIS' current evaluation system, products that are clearly at higher risk due to their potential health or environmental impacts are identified using a well established science based risk assessment process. We recommend that APHIS continue to utilize such an approach in exercising its oversight.

International Paper believes that a scientific approach where hypotheses are tested experimentally, objective data are accurately recorded and results are analyzed statistically is the optimal approach to assessing risk. This approach of evaluating risk on a case-by-case basis for a specific trade and a specific crop should continue to be applied to new products under development, including genetically modified tree species. Defining risk by categorical criteria or degree of familiarity is inconsistent with this approach and would strengthen

the protection of human health or the environment.

For example, we believe that this principle pertains to the regulation of well understood and extensively used plants. Familiarity with products produced from biotechnology should be established through science. New products entering the regulatory system may be unfamiliar to APHIS but may be well known and understood in the larger scientific community, based on the biology of the organism, trait and history of management practices. We recommend that APHIS use all available research data from lab work, greenhouse experimentation and field trials to assess product risk.

International Paper also believes that APHIS should not categorically regulate all nonviable genetically modified plant material, considering that such material could range all the way from raw logs and harvest residue to wood chips, lumber and even paper. Clearly, the risk is not constant along this path, and regulatory treatment of all this material should not be categorical.

International Paper does believe that APHIS should provide expedited review of commodities for import that have been properly approved in the country of origin, provided that the regulatory structure in

the country of origin is based on science.

With respect to regulatory flexibility, IP believes that any regulatory framework should have the flexibility to anticipate and keep pace with the evolving array of biotechnological tools that scientists are discovering and developing. APHIS' currently regulatory authority provides that flexibility while ensuring transparency and providing for public understanding of how products from biotechnology are tested and regulated.

Finally, with respect to container requirements, APHIS should move from a prescriptive container requirement for shipment of genetically engineered organisms to performance based requirements with supplemental guidance information. The current shipment of protocols are outdated and are perhaps more appropriate for material with low respiration rate, such as seed. They're not appropriate for other types of moving plant material with higher respiration rates.

The performance based standards should be adopted, because under some conditions, the correct prescriptive container types are detrimental or even lethal to the valuable plant material they contain.

In conclusion, I'd like to stress that

forest research breakthroughs, including those in biotechnology, are essential if the U.S. forest products industry is to remain globally competitive and our forests are to remain healthy and productive. Our industry has a long history of research in forest management expertise resulting from internal research programs and from a wealth of information generated by the greater scientific community.

We look forward to working with APHIS to find ways to apply biotechnology in the context of this experience, to use it to enhance forest productivity to meet the fiber needs of future generations. Thank you.

MR. TURNER: Do you have any questions about EIS or things that we could clarify that would be helpful for you in preparing your written comments?

MR. RAKESTRAW: I guess we would like to know a little bit more about the process, moving forward.

MR. TURNER: Environmental impact statements are often done by the government for major actions. You will have a proposal for an action, and you'll do an environmental impact statement. This is more akin to a programmatic EIS, but we're looking at a number of options and evaluating them, and hoping this large

study of potential acts to the environment will then inform the writing of the regulation, the rule as we call it. So we have the environmental impact statement out front, looking in programmatically at a broad number of issues and options with ways that we could proceed.

One of the nice things about it, one of the advantages we think with our notice of intent, and the next milestone will be a draft EIS. There's, we think, a lot of opportunity for public and stakeholder input up front, because under NEPA, the National Environmental Policy Act, it is a very open and public process. So that's why we've chosen to do it this way. We're looking to have maybe a draft EIS sometime in the fall and a proposed rule sometime during the fall.

MR. RAKESTRAW: So they're not simultaneous activities, the EIS precedes the rule?

MR. TURNER: Right, and there may be aspects of the rule writing that will start while the EIS process is going. But to some extent, the rule will lag behind the conclusive EIS.

MS. MANN: John, have you all considered from a process standpoint alerting the public during each of these steps so that folks like us would be

able to provide input in a timely and appropriate way? By the way, excuse me. I'm Mary Mann from the Washington office of IP.

MR. TURNER: We have tried to alert stakeholders, --

MS. MANN: Right.

MR. TURNER: -- but I guess we're open to suggestions if there are better alternatives, but NOI, of course, is published in the *Federal Register*. On that same day of the rollout, we held a number of stakeholder conference calls. There was, of course, a press release by the agency. The secretary was involved in the press release, and it was covered by the major newspapers. It was a pretty high profiled then. We anticipate to the extent we can that we'll call attention to the other major milestones.

There will be a public comment period on the draft EIS and on the proposed rule, in the same way that there was on the notice of intent. Also, during the rule making process, we're anticipating that we'll have public meetings, so we wanted to do what we can to invite the public and the stakeholders.

MS. MANN: A technical question, and I'm going to get very quickly out of my league here, so I'm going to defer to Jim, but as you all move forward

and assimilate the data for our industry, have you considered a baseline for how you're going to measure forestry activities?

I say that to bring notice upon a program that International Paper takes very seriously amongst the -- unless this is handled forestry initiative, then we can provide additional input with regards to that program, but it's a voluntary regulatory program to ensure the sustainable forestry management practices are in place and very active on all of our forest holdings. It may be something that you all might want to look at, moving forward.

MR. RAKESTRAW: I think there is a provision in the sustainable forestry initiative for biotechnology generally, although I think the wording is rather broad. But as we move forward, they would be very much interested and engaging, I think. That is, the SO5 program generally would be interested in engaging in this topic.

MR. TURNER: Let me see if I understand. When you say a "baseline of activities," is this a baseline that we would use in our assessments of forestry as being something you can do, what conventional braiding is, crop clearance?

MR. RAKESTRAW: Well, maybe one way to ask

the question would be, do you consider forestry to be different in any respect from agronomic crops?

MR. TURNER: Well, biologically, they're very different, which doesn't mean we necessarily think they're riskier, but obviously, the considerations are different, because it's a perennial. Some agronomic crops, not all, will only thrive and persist in the agri ecosystem. Corn and soybeans are the ultimate nonweeds. They won't grow except under cultivation. Other things, any things we're dealing with now that aren't free, such as grasses and all, have a shared characteristic with trees in that they're perennials and they could persist and establish elsewhere.

So it means the assessment needs to be different, not necessarily to say what the conclusion or the outcome would be. I think there will be an ongoing process on our part of it of gathering information about trees and considering input on how we will do the assessment, some of it directly relating to the rule making process, some of which has been going on since before this was initiated and will continue to go on after we have a rule. We're always looking for the best science with which to do our assessments.

MR. RAKESTRAW: Thank you.

MR. TURNER: We had a meeting on trees this past summer. It was not in conjunction with the new rule, but just to talk about issues and how we should go about evaluating this, what's the data package look like relative to agronomic core crops.

MS. MANN: Well, as we mentioned prior to the formal discussion this morning, if there's anything that International Paper can offer in the way of educational opportunities, perhaps a tour of some of our forestry operations or opportunities to meet with some of our foresters, spending more time in the field with Jim and others, we'd be happy to extend that and work with you and your staff to accommodate your schedules and see if we can make that work, as you go ahead and continue to flesh out the data collection process and moving forward with those proposed regulations.

MR. TURNER: Yeah, I think there's certainly some interest, and that's a possibility.

MR. RAKESTRAW: Great.

MS. KOEHLER: This work that you mentioned, you mentioned some acronym?

MR. RAKESTRAW: SFI, sustainable forestry initiative?

MS. KOEHLER: Okay. I thought there was something else that you mentioned. Was there something else?

MR. RAKESTRAW: I don't think so.

MS. KOEHLER: Okay. Maybe I was thinking -- I thought you said something that began with a C, but maybe I was confused.

MR. WACH: I had a question. Do you feel that the way you approach biotechnology now in IP, is there a good fit between that way you're going and the way our regulations work for you? Do you think that fit could be improved? Do you think it works really well for you now?

MR. RAKESTRAW: I think it works well.

MR. WACH: So you wouldn't want to propose any changes in time frames, data collection, environments, that kind of thing, based on the differences between trees and soybeans, for instance?

MR. RAKESTRAW: Well, obviously, they have different lifespans, and that would be a consideration in thinking about trees as opposed to annual crops. But in terms of the overall approach, I think we're pretty comfortable with the current framework. You know, I mentioned that the container issue might require some further thinking.

MR. WACH: You mentioned about some things could actually die in these containers. Do you have a specific example of that? Are you familiar?

MR. RAKESTRAW: A lot of tree material is actually handled in tissue culture, and those cultures often have high respiration rates, and provision probably should be made for accommodating that kind of material. Sealing it up in airtight containers generally does not work very well. It would be fine for seed.

MR. TURNER: Those are good things to hear, because as you know, that's one of the things we're considering is container requirements.

MS. KOEHLER: Your comment on the import issue, that's our question No. 8 in the NOI. Would you care to expand on that a little bit? I think you said you thought providing for some sort of expedited review is okay, as long as the other countries' reviews were science based. What was the other thing you said there?

MR. RAKESTRAW: That may be all that I said.

MS. KOEHLER: Okay.

MR. RAKESTRAW: Generally, I guess the point is that -- and I think John made this point earlier in his introductory remarks -- APHIS should be leading

the way in terms of setting precedents for other countries to follow, providing the example is a science based regulatory scheme. To the extent that other countries adopt that sort of approach, I think we ought to recognize it and probably make use of it in our own consideration for importation. That was my point.

MS. KOEHLER: Okay.

MR. TURNER: And that's an excellent point, that we want to lead the way and make sure their regulations are science based. Behind No. 8 is to some extent also this idea of reciprocity. We've been mostly exporting and asking other countries to accept our exports, because we've done the review and they may not have done them. Now for the first time, we're getting things coming in where if you may have been approved in that country, and they're asking us to do what we may have asked them to do in the past.

It's an interesting issue. If it's not going into the ground, it can't be a plant past or a noxious weed. If it were a commodity going straight to the mill, forced product may be viable in terms of it's respirating, but not for propagation can it be treated differently, so that's the idea behind the question. I guess we had actually thought mostly

about commodities.

MS. KOEHLER: Grain commodities.

MS. MANN: Do you all have any other questions?

MS. MCCAMMON: I have a question. It's a really small one. To follow up, you mentioned this idea that John just elaborated on in reciprocity. Do you have an idea of what form or have you thought about what form the international recognition might take, or what under auspices standard setting bodies? Do you have examples of how this has occurred in the past, other than chemicals?

MR. RAKESTRAW: Not offhand. We'll think about your question, though, and perhaps offer some suggestions in our written comments.

MS. MCCAMMON: Okay. Thank you.

MR. TURNER: I might offer just a tiny bit of clarification on the idea of the tiered categories for field testing. There's been a lot of discussion about that, pros and cons of. In a way, it's perhaps not as different as it first appears but somewhat building on our current system and that we have safety criteria for notifications and for certain things that meet those safety criteria. They are field tested under what are fairly relaxed standards, AOSCA

standards of distances and other things.

Other things that don't fit that have to get a permit, and then certain things under permit, if they're pharmaceuticals or industrials have very general requirements. So to some extent, it's new, but to some extent it's building on what we have. What tiering allows is for field testing to go forward before there's a lot of data or before there is an assessment based on some criteria that could be laid out beforehand, or else you're stuck with treating everything as very dangerous until you have an assessment.

So to some extent, our current system already allows us to pull out certain things that are likely to be at low risk and let field testing proceed. I think some stakeholders are worried about the concept. Some are more worried about what they go, you don't go in, and we're certainly open to both of those and recognize that what those criteria are, the things in those categories are very important.

MS. KOEHLER: Yeah, along that line, we were hoping to get comments on what kind of criteria could be used to establish those different categories. We had sort of proposed some examples of what those might look like. Those are just examples. There are many

ways to categorize things, based on science based risk criteria, so we're hoping to input on what you might think appropriate criteria might be for placing things in the categories, that we're going to place in the categories. That's Susan Koehler. I'm sorry. I keep forgetting to give my name.

MR. RAKESTRAW: Well, I don't know that we would be prepared to offer specific suggestions right now. I think one concern that we would have is that because trees don't fit the category of agronomic crops that are annual, they have very little possibility. Where a transgene has low probability of escape, say, into a wild population that trees, because they are long lived automatically are at high risk. I guess we would be a little bit concerned that the criteria be transparent.

Well, obviously, we wouldn't want them to be transparent and not based on a subjective understanding or a subjective perception that because organisms in some respect have different biology, they therefore are at high risk.

MS. MANN: Going to your previous question about the international standards of reciprocity, have you all given some thought to standards or formulas that you perhaps could share with us today that we

could factor into our thinking about this?

MS. MCCAMMON: John, did you want to answer what we did with Canada, or do you want me to?

MR. TURNER: Feel free.

MS. MCCAMMON: This is something that's come up a lot, and primarily more in the aspect of stuff that we're trying to export to other folks. We now have an international standard for food safety under the CODEX. However, We have thought about but not really come to any conclusion. Normally, the U.S. tries to assert its national prerogatives. We protect very carefully our prerogative to evaluate products coming into our country.

However, the country we work the most on in this kind of arena is Canada, but we've not come to any state where we would accept their review. We work with them informally. We are currently working in IPPC, and I assume that at some point in the future we'll be working in OIE or elsewhere on the animals. So I think we would be open to suggestions or other models of how this occurs. I know the U.S. works a lot of the OECD on the chemicals, and I think there's a lot of mutual acceptance of data that could be a prototype, but we're certainly a long way to reaching that kind of a model in biotech.

In fact, we haven't really explored it very much. So if you had some ideas or other models that we might consider, I think it certainly would be seriously considered, probably not in developing this reg, but our international status in biotechnology is something that the whole government is involved in continuously, because it's a top burner issue for trade. So that's not a direct yes or no answer, but it's something that's, I think, an interesting possibility for us.

MR. TURNER: That's been our general approach. I think that was a great answer, Sally, is to start with maybe a country like Canada where we know we have a lot in common and see if we can agree or harmonize on certain requirements. If we can, you can take it to a regional basis and hopefully gain some momentum and then get these in an international arena. Ultimately, we would like to have good science in the standards setting bodies, that they reflected our own thinking. Then if you could make sure the other companies were doing their reviews according to those standards, you'd be in a great position.

Then the other piece of that is we're very active in capacity building with countries that don't have such a well developed regulatory system of

bringing them up to speed and sharing our experience in how to do risk assessments. That's another piece of that puzzle.

MS. MANN: That's helpful. Thanks.

MS. KOEHLER: You mentioned some kind of third party certification -- could you talk a little more about that -- in your opening statement?

MR. RAKESTRAW: The sustainable forestry initiative is a set of principles that companies who are members of the American Forest and Paper Association agree to adhere to. The standards are now set by an external board representing a fairly diverse set of stakeholders, many from outside the forest products community. Annually, we have our activities certified by an independent audit, and that's true of actually all members of the sustainable forestry initiative.

MS. KOEHLER: So this just affects how the forests themselves are managed? Does it have to do with what takes place once the forest is harvested and processed or whatever?

MR. RAKESTRAW: Yeah. There are some provisions that would impact the handling of wood. If you'd like, I could forward to you a copy of those principles. I think I actually --

MS. MANN: We actually have them.

MR. RAKESTRAW: Great.

MS. MANN: We brought along our sustainable forestry report in case you all were interested in some easy reading and interesting. To your general question, it's the overall health of the forest, from planting to harvesting to biodiversity to streamside management. It's the whole host of forestry activities. It's not just --

MR. TURNER: Stewardship principles.

MS. MANN: Right. That's something that we could get a better sense visually if we were able to do some kind of tour or something along those lines to see where we do have the tapped reserves.

MS. KOEHLER: Yeah, that would be interesting, if you wanted to provide that for the record.

MR. RAKESTRAW: Okay. That will be fine. We'll leave this with you. This is a summary of the major points, but the principles themselves are actually rather long, but we can send them.

MS. KOEHLER: Okay.

MR. TURNER: Anyone have anything else they want to ask? Concerning our guests, we're here to answer questions, among other things. I feel

compelled. This has been very helpful.

MS. MANN: Good. Well, thank you for your time.

ALL: Thank you.

(Whereupon, at 11:20 a.m, the meeting was concluded.)

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REPORTER'S CERTIFICATE

TITLE: Stakeholders Meetings (IP)

DATE: March 11, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: March 11, 2004

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